



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|----------------------|-------------------------|------------------|
| 10/018,992 | 02/19/2003 | Raffael Lahav | D01/200 | 2589 |
| 7590 12/06/2005 MARTIN D. MOYNIHAN PRTSI, INC. P. O. BOX 16446 ARLINGTON, VA 22215 | | | EXAMINER OH, SIMON J | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 1618 | |

DATE MAILED: 12/06/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/018,992

Applicant(s)

LAHAV ET AL.

Examiner

Simon J. Oh

Art Unit

1618

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 September 2005.
2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 40-91 is/are pending in the application.
4a) Of the above claim(s) _____ is/are withdrawn from consideration.
5) ☐ Claim(s) _____ is/are allowed.
6) ☒ Claim(s) 40-91 is/are rejected.
7) ☐ Claim(s) _____ is/are objected to.
8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Papers Received

Receipt is acknowledged of the applicant's amendment and response, both received on 29 September 2005.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

The rejection of Claims 40-90 under 35 U.S.C. 103(a) over the combined disclosures of Heese *et al.* and Bergstrand *et al.* are maintained.

Claim 91 is rejected under 35 U.S.C. 103(a) as being unpatentable over the combined disclosures of Heese *et al.* (U.S. Patent No. 6,623,759) and Bergstrand *et al.* (U.S. Patent No. 5,817,338)

The Heese *et al.* patent discloses benzimidazole derivative compositions comprising a core and a neutralized enteric coating. Specific benzimidazole derivatives that are deemed suitable for the disclosed compositions include omeprazole, lansoprazole, and pantoprazole (See Abstract). Various materials may be used for the enteric coating, including cellulose acetate phthalate and polymethacrylates (See Column 6, Lines 5-20). The enteric coating may contain a plasticizer such as triethyl citrate (See Column 7, Lines 5-9). The enteric coating is preferably applied as an aqueous dispersion and neutralized to a pH value of around 5.5 to around 7.0 (See Column 6, Lines 62-67). Suitable bases that may be used to neutralize the enteric coating

Art Unit: 1618

include sodium hydroxide and potassium hydroxide (See Column 5, Lines 12-20). Tests for the disclosed formulations are described where coatings other than HPMCP are used (See Examples 1 and 2).

The Heese *et al.* does not teach the use of a drug core where the active substance is layered over an inert core.

The Bergstrand *et al.* patent teaches a multiple unit dosage form of omeprazole (See Abstract). Each individual unit comprises a drug core and an enteric coating (See Column 4, Lines 2-9). The drug core may be formed from inert cores, with the active ingredient layered over them. The active substance may be mixed with other substances before being layered over the inert core, such as binders. Suitable binders include hydroxypropylmethylcellulose and hydroxylpropylcellulose (See Column 4, Lines 39-67). Suitable enteric coating layer materials include methacrylic acid copolymers, hydroxypropylmethylcellulose acetate succinate, cellulose acetate phthalate, and carboxymethylethylcellulose. Plasticizers may be included in the enteric coating layers, such as citric acid esters and phthalic acid esters (See Column 6, Lines 45-64). Although intermediate layers between the core and the enteric coating layer may be used, the prior art does contemplate embodiments where the enteric coating layer is applied directly over the drug core (See Column 5, Lines 60-67; and Example 8).

It would be obvious to one of ordinary skill in the art to combine the teachings Heese *et al.* and Bergstrand *et al.* into the objects of the instant application. The prior art references both disclose enteric-coated compositions of benzimidazole derivatives, and are therefore considered by the examiner to be analogous art for application against the instant claims. One of ordinary skill in the art would be motivated to combine the disclosures of the prior art references in order

Art Unit: 1618

to incorporate the neutralized enteric coating layer of Heese *et al.* directly over the drug cores disclosed in Bergstrand *et al.* so that such an embodiment can be made more stable and therefore, more advantageous over what has been previously been disclosed in the prior art. It is the position of the examiner that as the prior art references are analogous art, they can therefore be combined with a reasonable expectation of success in forming stable benzimidazole derivative compositions. Thus, the instantly claimed invention is *prima facie* obvious.

Response to Arguments

Applicant's arguments filed 29 September 2005 have been fully considered but they are not persuasive.

The examiner disagrees with the applicant's interpretation of the prior art. The composition described in the Heese *et al.* patent discloses a core coated with a polymer layer that is neutralized to a range of pH 5.5 to 7.0, as well as being resistant to gastric acid. Therefore, it has the functional properties of an enteric coating layer. Furthermore, there is no additional layer that exists between that neutralized enteric coating layer and the core. Therefore, in the view of the examiner, the disclosure of the Heese *et al.* patent, in combination with the Bergstrand *et al.* patent, reads on the instantly claimed invention.

In ascertaining the scope of the instantly claimed invention, the examiner has interpreted the instant claims to be drawn to a composition that comprises a substrate in the form of a core that contains the active agent, that is coated with an enteric coating layer neutralized to a pH of at least about 6.5, with no intermediary layer between the neutralized enteric coating and the substrate. However, in the view of the examiner, the open scope of the claim language does not

Art Unit: 1618

forbid the inclusion of additional outer coating layers over the neutralized enteric coating layer.

In the view of the examiner, it is this embodiment that is substantially presented by the Heese *et al.* patent.

Again, the examiner would like to emphasize that the coating layer that is in direct contact with the core of the composition described in the Heese *et al.* patent is a neutralized enteric coating layer. In the view of the examiner, such a characterization elevates that coating layer above a mere intermediary layer, because of its functional properties, and reads on the enteric coating layer recited in the instant claims. While the applicant may not agree with the examiner's reasoning, the examiner would like to further point out that the applicant has also defined the enteric coating material recited in the instant claims along the same sort of limitations. That is, the applicant has chosen to define the instantly recited enteric coating layer primarily through functional language. Thus, it is assumed that applying a prior art rejection along the lines of functional language would be considered proper. All pending claims are therefore rejected.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after

Art Unit: 1618

the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Correspondence

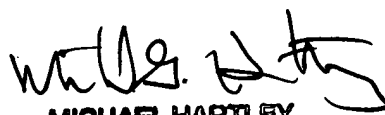
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Simon J. Oh whose telephone number is (571) 272-0599. The examiner can normally be reached on M-F 8:30 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Simon J. Oh
Examiner
Art Unit 1618

sj0


MICHAEL HARTLEY
PRIMARY EXAMINER